

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

BEVERLY RUSSO and
GEORGE POMFRET

Plaintiffs,

v.

COLOPLAST CORP.,

Defendant.

Civil Action No.: 1:20-cv-11819

PLAINTIFFS' COMPLAINT AND JURY DEMAND

COMES NOW the Plaintiffs, BEVERLY RUSSO and GEORGE POMFRET, and files this Original Complaint against the Defendant Coloplast Corp., (hereinafter referred to as "Coloplast") as follows:

I. INTRODUCTION

1. This is an action for damages suffered by BEVERLY RUSSO ("Plaintiff"), and Plaintiff GEORGE POMFRET as a direct and proximate result of Coloplast's wrongful conduct in connection with the development, design, manufacture, marketing, distribution and selling of Coloplast's Pelvic Mesh Products¹ inserted in her body to treat medical conditions, primarily stress urinary incontinence.

2. Plaintiff, by her undersigned counsel, brings this action against Coloplast related to the design, manufacture, marketing, distribution and sale of Defendant's Coloplast T-sling. This action is for compensator, equitable, injunctive, and declaratory relief. Plaintiff is making the

¹ The term Pelvic Mesh Products includes Coloplast's mesh, hammock and sling products used to treat pelvic organ prolapse and/or stress urinary incontinence. The term Pelvic Mesh Products also specifically includes the Coloplast products implanted into Plaintiff, which is the Coloplast T-Sling (hereinafter "Mesh Products").

following allegations based upon her individual personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Coloplast's actions and misconduct, and alleges as follows:

II. PARTIES

3. Plaintiffs BEVERLY RUSSO and GEORGE POMFRET are citizens of the Commonwealth of Massachusetts, County of Middlesex, and the City of Waltham.

4. Defendant Coloplast Corp. ("Coloplast Corp.") is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411. Coloplast Corp. is a wholly owned U.S. sales and marketing subsidiary of Coloplast A/S.

III. JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs BEVERLY RUSSO and GEORGE POMFRET exceed \$75,000.00, exclusive of interest and costs, and because Defendant are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

6. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 in that Defendant conducts business here and is subject to personal jurisdiction in this District. Furthermore, Defendant sells, markets, and/or distributes their Pelvic Mesh Products within Massachusetts and this District.

IV. FACTUAL ALLEGATIONS **COLOPLAST PELVIC MESH PRODUCTS BACKGROUND**

8. Coloplast develops, designs, manufactures, labels, packages, distributes, markets,

supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution Pelvic Mesh Product medical devices for the treatment of medical conditions in the female pelvic, primarily pelvic organ prolapse and stress urinary incontinence.

9. At all times relevant, transvaginal meshes were used to treat pelvic organ prolapse and stress urinary incontinence.

10. A pelvic organ prolapse occurs when a pelvic organ, such as a bladder, drops (“prolapses”) from its normal position and pushes against the wall of the vagina. Prolapses can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum. Stress urinary incontinence is a type of incontinence caused by leakage of urine during moments of physical stress. It affects 20-40% of all women.

11. Surgical mesh, including transvaginal mesh, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or nonabsorbable synthetic material and absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most transvaginal meshes are comprised of non-absorbable synthetic polypropylene. Upon information and belief, the Pelvic Mesh Products are comprised of a synthetic, petroleum-based mesh.

12. Coloplast’s Pelvic Mesh Products, including the Coloplast T-Sling, were derived from polypropylene mesh products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

13. In 1996, the FDA cleared the first mesh product for use in the treatment of stress

urinary incontinence (SUI). These products include transvaginal mesh, including the Coloplast T-Sling manufactured, marketed and distributed by Coloplast. These products are approved by the FDA under the abbreviated 510(k) approval process.

14. Coloplast's website describes its various products, including those for treating (i) "Pelvic Organ Prolapse" and (ii) "Stress Urinary Incontinence", including "Sling Procedures." A press release issued by Coloplast described Coloplast's new corporate headquarters at 1601 West River Road in Minneapolis and stated that "Denmark-based Coloplast...selected north Minneapolis as the new home for its North American headquarters in 2006." According to the press release the new headquarters "will include one of the company's three global Innovation Centers."

15. Coloplast develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells and otherwise engages in all activities that are part and parcel of the sale and distribution medical devices, including medical devices implanted to treat certain women, like Plaintiff, for pelvic organ prolapse and stress urinary incontinence such as the Coloplast Coloplast T-Sling (hereinafter "Products"). The Pelvic Mesh Products known as Coloplast T-Sling as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Coloplast's Pelvic Mesh Products or the Pelvic Mesh Products.

16. Coloplast's Pelvic Mesh Products, including the Pelvic Mesh Products specifically used for Plaintiff, have been and continue to be marketed to the medical community and to patients as safe, effective, reliable medical devices implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence. Coloplast markets the Pelvic Mesh Products, including the Product

specifically used for Plaintiff, as safer and more effective when compared to 1) the traditional products and procedures for treatment of pelvic organ prolapse and stress urinary incontinence and 2) other competing pelvic mesh and sling products.

17. Coloplast made public statements in the form of written product descriptions, product labels, promotional materials, marketing materials and other materials that asserted that implanting the Pelvic Mesh Products in patients was safe and would not cause harm to patients, like Plaintiff. Coloplast has also marketed and sold its Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, telephone information lines, and training offering exaggerated and misleading expectations as to the safety and utility of the Coloplast's Pelvic Mesh Products.

18. Contrary to Coloplast's representations and marketing to the medical community and to the patients themselves, Coloplast's Pelvic Mesh Products, including the Coloplast T-Sling have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating reoperations, and have caused severe and irreversible injuries, conditions, and damage to the Plaintiff. These defects include, but are not limited to:

- a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.
- b. The mesh material harbors infections that adversely affect human tissues and patient health.

- c. The Pelvic Mesh Products migrate from the location of their implantation, adversely affecting tissues and patient health.
- d. The mesh material abrades tissues adversely affecting patient health.
- e. The Pelvic Mesh Products regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.
- f. Due to their various defects, the Pelvic Mesh Products regularly cause significant injury to patients such that the Pelvic Mesh Products must be removed, resulting in additional surgery.
- g. The Pelvic Mesh Products become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health.
- h. The Pelvic Mesh Products are defective in shape, composition, weight, physical, chemical and mechanical properties and is inappropriately engineered for use in the female pelvis.
- i. The Pelvic Mesh Products erode into other pelvic organs, tissue, muscle, nerves, and bone adversely affecting tissues and patient health.

19. Because of their numerous defects, the Pelvic Mesh Products, including the Coloplast T-Sling, create an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and

fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to the woman's intimate partner.

20. Coloplast made, participated in and/or contributed to filings with the Food and Drug Administration in conjunction with the clearance process and other filing requirements for Coloplast's Pelvic Mesh Products.

21. Upon information and belief, Coloplast sent to the FDA a 510(k) submission for its Pelvic Mesh Products.

22. Upon information and belief, Coloplast was in control of designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling and issuing of product warnings and related information with respect to its Pelvic Mesh Products.

23. Coloplast has consistently underreported and withheld information about the propensity of its Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, Plaintiff's implanting physician, patients and the public at large.

24. Coloplast has known and continues to know that its disclosures to the FDA were and are incomplete and misleading; and that its Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. Coloplast suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with

the FDA, health care providers, Plaintiff's implanting physician, or the patients. As a result, Coloplast actively and intentionally misled and continue to mislead the public, including the medical community, Plaintiff's implanting physician, health care providers and patients, into believing that its Pelvic Mesh Products were and are safe, effective, and would not cause harm to patients. These statements were made with the intent that medical professionals and members of the public would rely upon them, with the intent that members of the public would pay for the Pelvic Mesh Products and that the Pelvic Mesh Products would be implanted in patients. When Coloplast made these statements, Coloplast knew or should have known that the statements were inaccurate.

25. Coloplast has at all times provided incomplete, insufficient, and misleading training and information to physicians, including Plaintiff's implanting physician, in order to increase the number of physicians utilizing the Coloplast's Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

26. Coloplast was at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the clearance process, labeling and other marketing activities that pertain to the its Pelvic Mesh Products.

27. Coloplast failed to perform or rely on proper and adequate testing and research in order to determine the safety and effectiveness of its Pelvic Mesh Products.

28. Coloplast failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the its Pelvic Mesh Products.

29. Coloplast failed to design and establish a safe, effective procedure for removal of

its Pelvic Mesh Products; therefore, in the event of a failure, injury, or complication it is impossible to easily and safely remove Coloplast's Pelvic Mesh Products.

30. Feasible, safer, and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Coloplast's Pelvic Mesh Products. These feasible, safer, and suitable alternatives include but are not limited to: the use of sutures, including delayed absorbable sutures like PDS, in colposuspension procedure like the Burch, autologous facia sling, allograft sling such as Repliform, and a sling with less polypropylene such as Ultrapro.

31. Coloplast's Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Coloplast.

32. The Pelvic Mesh Products implanted into the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Coloplast, and in the condition directed by Coloplast.

33. The injuries, conditions and complications suffered due to Coloplast's Pelvic Mesh Products include but are not limited to mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, prolapse of organs, and in many cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the

female genitalia, and injuries to the woman's intimate partner.

34. Despite Coloplast's knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, including the Coloplast T-Sling, Coloplast has, and continues to manufacture, market and sell the Pelvic Mesh Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to Coloplast's Pelvic Mesh Products, both prior to and after the marketing and sale of the Pelvic Mesh Products.

35. Prior to the time that the Coloplast T-Sling implanted into Plaintiff, Coloplast was aware of numerous defects in the Pelvic Mesh Products, including, but not limited to, the defects and unreasonable risks identified above. Based thereon, Coloplast knew or should have known that the Pelvic Mesh Products caused an unreasonably high rate of complications, such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs in women implanted with the Pelvic Mesh Products. Despite being aware of the numerous defects and unreasonable risks in its products, Coloplast developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products with the intent that it would be implanted in patients. Coloplast was aware that implanting the Pelvic Mesh Products, including the Coloplast T-Sling in patients was likely to cause injury and harm to the patients into whom the Pelvic Mesh Products were implanted. Alternatively, Coloplast failed to exercise reasonable care in determining the risks and potential adverse consequences of implanting the Products into patients.

36. Even though Coloplast has known or should have known that the Pelvic Mesh Products created a foreseeable, unreasonable risk of harm to those women into whom they were implanted, Coloplast continued to market the Pelvic Mesh Products in the United States. Coloplast has sold thousands of Pelvic Mesh Products in the United States alone.

37. Coloplast has failed to provide adequate warning or information about the risks that the Pelvic Mesh Products, including the Coloplast T-Sling, cause an unreasonably high rate of complications, including mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs to physicians who implanted the Pelvic Mesh Products, including Plaintiff's implanting physician, or to women implanted with the Pelvic Mesh Products.

V. CASE SPECIFIC ALLEGATIONS

38. On or about February 13, 2012, at Newton-Wellesly Hospital, Massachusetts, Plaintiff underwent the implantation of a Coloplast Pelvic Mesh Products, that being the Coloplast T-sling, to treat her urinary incontinence.

39. Prior to Plaintiff's surgery, her implanting physician, as well as Plaintiff, was exposed to the aforementioned advertising and marketing campaign directed by Coloplast.

40. Plaintiff and her implanting physician, either through direct promotional contact with Coloplast Sales Representatives, Lab Faculty, through word-of-mouth with other health care providers, and/or through promotional materials, received the information Coloplast intended Plaintiff and her implanting physician to receive and view, to wit: that the Coloplast T-Sling was safe and effective for use in the treatment of pelvic organ prolapse and stress urinary incontinence.

41. Plaintiff began experiencing severe and debilitating abdominal pain, vaginal bleeding, chronic urinary tract infections, urinary incontinence, dyspareunia, dysuria, hematuria, urinary frequency, lethargy, and mesh erosion some time after implant.

42. Plaintiff sought medical care from her physicians due to complications and problems attributed to the Coloplast T-Sling and was diagnosed with “erosion of vaginal mesh.”

43. On September 14, 2020, Plaintiff underwent surgery at BWF Main Hospital in Massachusetts to remove the Coloplast T-Sling.

44. Had Plaintiff’s physician been adequately warned of the risks and dangers of Coloplast’s Coloplast T-Sling, Plaintiff’s implanting physician would not have recommended the implantation of the Coloplast T-Sling inside of Plaintiff and Plaintiff would not have consented to the implantation of the Coloplast T-Sling inside of her body.

45. As a direct and proximate result of the use of the Coloplast Pelvic Mesh Products, Plaintiff suffered, and continues to suffer, serious bodily injury and harm. It was not until recently that Plaintiff learned the Coloplast Pelvic Mesh Products were defective and the cause of her pain, suffering, and complications.

46. As a direct and proximate result of the use of the Coloplast Pelvic Mesh Products, that being the Coloplast T-Sling, Plaintiff incurred, and continues to incur, medical expenses to treat her injuries and condition.

47. As a direct and proximate result of the use of the Coloplast Pelvic Mesh Products, that being the Coloplast T-Sling, Plaintiff continues to receive medical treatment and is anticipated to undergo further surgeries to remove more mesh.

Fraudulent Concealment

48. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through affirmative misrepresentations and omissions, actively concealed from Plaintiff, physicians, the medical community, and the general public the true risks associated with Coloplast Pelvic Mesh Products.

49. As a result of Defendant's actions, Plaintiff and physicians were unaware, and could not reasonably have known or have learned through reasonable diligence, that they had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

CAUSES OF ACTION - THEORIES OF RECOVERY

COUNT I

PRODUCT LIABILITY ACT – DEFECTIVE DESIGN

50. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

51. The aforementioned design defects in the Pelvic Mesh Products implanted in Plaintiff existed from their manufacture; therefore the defects were present when they left the possession and control of Coloplast. The Coloplast T-Sling was used by Plaintiff in a reasonably foreseeable and intended manner.

52. The Plaintiff is an expected and ordinary user or consumer of the Coloplast T-Sling.

53. At the time of manufacture and conveyance, the Coloplast T-Sling failed to meet the minimum safety expectations of the ordinary user and consumer: Plaintiff expected the Mesh Product would treat and/or remedy her urinary incontinence, without causing the aforementioned serious and painful complications.

54. The Mesh Products implanted in Plaintiff was, at the time of manufacture and

conveyance, not in conformity with the generally recognized state of the art applicable to the safety of the Mesh Products at the time it was designed, manufactured packaged, labeled and/or sold.

55. Coloplast's Pelvic Mesh Products were "defective", unfit, unsafe, inherently dangerous and "unreasonably dangerous" for their intended and reasonably foreseeable uses. The Coloplast T-Sling was in said condition when it entered the stream of commerce and was received by Plaintiff. The Coloplast T-Sling did not meet or perform to the expectations of patients, including Plaintiff, and their health care providers, including Plaintiff's implanting physician. The Coloplast T-Sling was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

56. The Coloplast T-Sling implanted in Plaintiff was not reasonably safe for its intended uses and was defective as described herein with respect to their design. As previously stated, Coloplast T-Sling's design defects include, but are not limited to:

- a. the use of polypropylene material in the Coloplast T-Sling and the immune reaction that results from such material, causing adverse reactions and injuries;
- b. the design of the Coloplast T-Sling to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
- c. biomechanical issues with the design of the Coloplast T-Sling, including, but not limited to, the propensity of the Coloplast T-Sling to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

- d. the use and design of arms and anchors in the Coloplast T-Sling, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;
- e. the propensity of the Coloplast T-Sling to “creep,” or to gradually elongate and deform when subject to prolonged tension inside the body;
- f. the inelasticity of the Coloplast T-Sling, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);
- g. the propensity of the Coloplast T-Sling for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;
- h. the hyper-inflammatory responses to polypropylene leading to problems including chronic pain and fibrotic reaction;
- i. the adverse tissue reactions caused by the polypropylene products, which are causally related to infection, as the polypropylene is a foreign material in the body;
- j. the harshness of cross-linked polypropylene upon the female pelvic tissue, and the hardening of the product in the body; and
- k. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

57. Safer, feasible and practical alternatives to the Mesh Products implanted in Plaintiff have existed at all times relevant, including at the time of manufacture and conveyance,

that were available to the Defendant that do not present the same frequency or severity of risks as do the Mesh Products implanted in Plaintiff. These safer feasible and practical alternatives include but are not limited to:

- a. The use of sutures, including delayed absorbable sutures like PDS, in
- b. autologous facia sling;
- c. an allograft sling such as Repliform;
- d. a sling with less polypropylene such as Ultrapro
- e. collagen or biological material suspension products;
- f. corrective surgery without the use of mesh; and
- g. colposuspension procedure like the Burch

58. The Pelvic Mesh Products create risk to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

59. The burden and cost of implementing safer, feasible, and alternative designs would not have outweighed the reduction of injury caused to consumers, including Plaintiff,

60. Coloplast has intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Pelvic Mesh Products with wanton and willful disregard for the rights and health of the Plaintiffs and others, and with malice, placing their economic interest above the health and safety of the Plaintiff and others.

61. The Pelvic Mesh Products used by Plaintiff's physician were not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The subject Pelvic Mesh Products reached the Plaintiff in such a condition that was unreasonably dangerous to her.

The Coloplast Pelvic Mesh Products were used in the manner for which it was intended, that is, for treatment of pelvic organ prolapse and/or stress urinary incontinence. This use resulted in injury to Plaintiff.

62. At no time did Plaintiff have reason to believe that Pelvic Mesh Products were in a condition not suitable for its proper and intended use among patients.

63. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the Pelvic Mesh Products. Further, in no way could Plaintiff have known that Coloplast had manufactured the Pelvic Mesh Products in such a way as to increase the risk of harm or injury to the recipients of the implant.

64. As a direct and proximate result of the Mesh Products' aforementioned design defects, Plaintiff experienced painful and serious complications, including but not limited to, chronic urinary tract infections; dyspareunia; lethargy; constant, excruciating abdominal pain; vaginal bleeding; urinary frequency, incontinence, dysuria, hematuria, and mesh erosion as a result of the Coloplast T-Sling being implanted in her.

65. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT II
PRODUCT LIABILITY ACT - FAILURE TO WARN

66. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

67. The Pelvic Mesh Products were defective by reason of failure of Coloplast to provide adequate warnings or instructions.

68. Coloplast failed to properly and adequately warn and instruct the Plaintiff and her implanting physician as to the proper candidates, if any, and the safest and most effective methods of implantation and use of Coloplast's Pelvic Mesh Products.

69. Coloplast failed to properly and adequately warn and instruct the Plaintiff and her implanting physician as to the aforementioned risks and benefits of Coloplast's Pelvic Mesh Products, given the Plaintiff's condition and need for information.

70. Coloplast failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

71. Coloplast failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Pelvic Mesh Products or to those women who had been implanted with the Pelvic Mesh Products, concerning the following risks, including the severity and frequency of the risks, given their condition and need for information. Coloplast had actual or constructive knowledge of the following risks at the time the Pelvic Mesh Products left Coloplast's control and was being marketed:

- a. The high failure rate of the Pelvic Mesh Products;
- b. The high rate of infections and abscesses caused by the Pelvic Mesh Products;
- c. The high rate of vaginal erosions and extrusions caused by the Pelvic Mesh

Products;

- d. The high rate of chronic pain caused by the Pelvic Mesh Products;
- e. The necessity to remove the Pelvic Mesh Products from the patient's body in the event of product failure, infections, abscesses, erosion, extrusion or other complication; and
- f. The difficulty in removing the Pelvic Mesh Product from the patient's body, including the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

72. After receiving notice of numerous bodily injuries resulting from the Pelvic Mesh Products, Coloplast failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Pelvic Mesh Products or those women who had been implanted with the Pelvic Mesh Products that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic, and other acute and chronic nerve damage and pain, pudendal nerve damage, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse of organs. Furthermore Coloplast failed to provide post-marketing or post-sale warnings to instructions concerning the necessity to remove the Pelvic Mesh Products from the patient's body in the event of the product failure or other complications.

73. Coloplast intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the Coloplast Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the

rights and health of the Plaintiff.

74. At the time of manufacture and conveyance, Defendant, by exercising reasonable diligence, could have made the aforementioned warnings regarding the Mesh Products available to Plaintiff, Plaintiff's implanting physician, and the medical community.

75. Absence of a warning or instruction renders the product unreasonably dangerous for its intended use.

76. Had Defendant adequately warned Plaintiff's implanting physician of the aforementioned risks, complications, and dangers associated with the Mesh Products, Plaintiff's physician would have recommended more feasible, safer and suitable alternatives to the Plaintiff, and Plaintiff's injuries could have been avoided.

77. Had Defendant adequately warned Plaintiff's implanting physician of the risks and dangers associated with the Mesh Products, Plaintiff would not have consented to the implantation of the Mesh Products inside her body and would not have suffered the aforementioned injuries.

78. As a direct and proximate result of Defendant's failure to provide Plaintiff, Plaintiff's implanting physician, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's implanting physician were not adequately informed of the potential dangers and/or defects of the Mesh Products.

79. As a direct and proximate result of the Defendant's failure to adequately warn Plaintiff, her implanting physician, and the medical community of the aforementioned risks and dangers of the Mesh Products as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained the aforementioned injuries, has undergone medical treatment, including multiple procedures to correct her injuries, and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not

limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT III
NEGLIGENCE

80. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

81. At all times relevant herein, Coloplast had a duty to exercise reasonable and ordinary care in the development, design, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products, including a duty to ensure that the Pelvic Mesh Products did not pose a significantly increased risk of bodily injury to its users.

82. Coloplast had a duty to exercise reasonable care in the advertising and sale of the Pelvic Mesh Products, including a duty to warn and instruct Plaintiff and other consumers, of the dangers associated with the use of the Pelvic Mesh Products that were known or should have been known to Coloplast at the time of the sale of the Pelvic Mesh Products to the Plaintiff.

83. Coloplast had a duty to exercise reasonable and ordinary care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

84. Coloplast knew or should have known Plaintiff could foreseeably suffer injury as a result of Coloplast's failure to exercise ordinary care as described above.

85. Coloplast failed to warn the general public, including Plaintiff, of the risk of serious harm.

86. Coloplast breached their duty to Plaintiff by failing to exercise due care under the circumstances.

87. Coloplast failed to exercise ordinary and reasonable care in the development,

design, manufacture, label, packaging, instructions, warnings, sale, distribution, marketing, supply, advertisement, selling and other activities that are part and parcel of the sale and distribution of the Pelvic Mesh Products. Coloplast was negligent in that they failed to provide adequate warnings and instructions to Plaintiff or to her physician regarding the Pelvic Mesh Products. Coloplast further breached their duty of care in the recruitment and training of physicians to implant the Pelvic Mesh Products.

88. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's negligent design, manufacture, labeling, marketing, sale and distribution of Pelvic Mesh Products, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT IV
BREACH OF IMPLIED WARRANTY: CHAPTER 106, SECTION 2-314

89. Plaintiff hereby incorporates by reference and reavers each and every allegation contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

90. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted and sold the Coloplast Pelvic Mesh Products.

91. At all relevant times, Coloplast intended that the Coloplast Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Coloplast impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

92. Coloplast was aware that consumers, including Plaintiff and/or Plaintiff's physicians, would implant the Coloplast T-Sling in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of Coloplast's Pelvic Mesh Products.

93. The Coloplast Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff and her implanting physician, without substantial change in the condition in which it was manufactured and sold by Coloplast.

94. At all relevant times, Plaintiff and/or her implanting physicians used the Coloplast Pelvic Mesh Products for the purpose and in the manner intended by Coloplast.

95. At all relevant times, Coloplast was aware that consumers, including Plaintiff, would use the Coloplast Pelvic Mesh Products; which is to say that Plaintiff was a foreseeable user of the Coloplast Pelvic Mesh Products.

96. Plaintiff and/or her physicians were at all relevant times in privity with Coloplast.

97. The Coloplast Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they manufactured and sold Coloplast Pelvic Mesh Products.

98. Coloplast breached various implied warranties with respect to the Coloplast Pelvic Mesh Products, including the following particulars:

- a. Coloplast represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that the Coloplast Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Pelvic Mesh Products;
- b. Coloplast represented that the Coloplast Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Coloplast Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

c. Coloplast represented that the Coloplast Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy.

99. In reliance upon Coloplast's implied warranty, Plaintiff used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted and marketed by Coloplast.

100. Plaintiff and Plaintiff's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

101. Coloplast breached its implied warranties to Plaintiff in that the Coloplast T-Sling was not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

102. The Coloplast T-Sling implanted in Plaintiff failed to function as intended and as represented by Coloplast because it did not relieve the symptoms or otherwise alleviate the medical products they were intended to cure. Instead, the Pelvic Mesh Products caused Plaintiff to suffer severe and debilitating pain, mesh erosion, exposure/extrusion/protrusion, infections, bleeding, dyspareunia, bladder problems and other severe adverse health consequences. Because the Pelvic Mesh Products failed to conform to representations and were not suitable for the purpose for which they were used, Coloplast has breached its implied warranties.

103. Coloplast breached their implied warranty to Plaintiff in that the Coloplast Pelvic Mesh Products were not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of Common Law principles.

104. As a direct and proximate result of Coloplast's wrongful conduct, including Coloplast's breach of implied warranty, Plaintiff has sustained and will continue to sustain severe

and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

COUNT V – CHAPTER 93A CONSUMER PROTECTION ACT

105. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

106. Pursuant to Massachusetts statute codified at General Laws chapter 93A, § 2(c), the Attorney General of the Commonwealth has promulgated a regulation that states: “it shall be an unfair and deceptive act or practice to fail to perform or fulfill any promises or obligations arising under a warranty.” The implied warranty of merchantability is specifically included in the definition of a “warranty.” As a result, plaintiffs can invoke chapter 93A in product liability cases.

107. Plaintiffs are entitled to recover the value of attorney fees incurred in prosecuting their implied warranty claim.

108. Defendant is liable for double or treble damages, if in bad faith, it fails to make a reasonable offer of settlement after receiving a demand letter or has reason to know that its conduct violated General Laws Chapter 93A.

COUNT VI: LOSS OF CONSORTIUM

109. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

110. As a direct and proximate result of the above-described injuries sustained by Plaintiff BEVERLY RUSSO, where applicable, her spouse, GEORGE POMFRET, has suffered loss of consortium, companionship, society, affection, services and support.

**COUNT VII:
PUNITIVE DAMAGES**

111. Plaintiff hereby incorporates by reference and reavers each and every allegation

contained in the foregoing paragraphs of this Complaint as if fully set forth herein and further states and alleges as follows:

112. At all times relevant hereto, Coloplast knew or should have known that the Coloplast Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

113. At all times material hereto, Coloplast attempted to misrepresent and did misrepresent facts concerning the safety of the Coloplast Pelvic Mesh Products.

114. At the time Coloplast designed, manufactured, marketed, labeled, packaged, and sold the dangerous and defective Pelvic Mesh Products and failed to adequately warn Plaintiff of the dangerous and defective nature of the Pelvic Mesh Products and thereby caused Plaintiff's injuries, Coloplast knew, or in the exercise of the appropriate degree care should have known, that its conduct created an extreme degree of risk of serious injury to others and thereby showed complete and reckless indifference to, and conscious disregard for the safety of others, including Plaintiffs, and such conduct warrants the imposition of punitive damages under all applicable legal standards.

115. Coloplast's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Coloplast Pelvic Mesh Products.

116. At all times material hereto, Defendant knew and recklessly disregarded the fact that the Coloplast Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative methods, products and/or procedures and/or treatments.

117. At all times material hereto, Coloplast knew and recklessly disregarded the fact that the Coloplast Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

118. At all times material hereto, Coloplast intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk the risk of injuries caused by the Coloplast Pelvic Mesh Products.

119. Notwithstanding the foregoing, Coloplast continues to aggressively market the Coloplast Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there were safer alternatives.

120. Coloplast knew of the Coloplast Pelvic Mesh Products' defective and unreasonable dangerous nature, but continues to manufacture, produce, assemble, market, distribute, and sell the Coloplast Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Coloplast Pelvic Mesh Products.

121. Coloplast continues to intentionally and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Coloplast Pelvic Mesh Products in order to ensure continued and increased sales.

122. Coloplast intentionally, recklessly, and/or grossly negligent failure to disclose information deprived Plaintiffs of necessary information to enable them to weigh the true risks of using the Coloplast Pelvic Mesh Products against their benefits.

123. As a direct and proximate result of Coloplast's wrongful conduct, including the acts and omissions listed above, Plaintiffs have sustained and will continue to sustain severe and

debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

WHEREFORE, Plaintiffs pray for relief against Defendant, Coloplast Corp., as follows:

- a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to totally compensate Plaintiffs for all of their injuries and damages, both past, present and future;
- b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, lost income, loss of earning capacity, permanent disability, and pain and suffering;
- c. Restitution and disgorgement of profits;
- d. Punitive damages;
- e. Attorneys' fees, expenses, and costs of this suit;
- f. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
- g. Such other relief, monetary or equitable, as this Court deems necessary, just and proper

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands a trial by jury on all counts and as to all issues.

Dated: October 7, 2020

Respectfully submitted,
Beverly Russo and George Pomfret,
By their attorneys,

/s/ Benjamin H. Duggan
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